DEPARTMENT OF THE NAVY
NAVAL HOSPITAL
BOX 788250
MARINE CORPS AIR GROUND COMBAT CENTER
TWENTYNINE PALMS, CALIFORNIA 92278-8250

IN REPLY REFER TO:
NAVHOSP29PALMSINST 6700.10C
Code 0107
16 December 1996

NAVAL HOSPITAL TWENTYNINE PALMS INSTRUCTION 6700.10C

From: Commanding Officer

Subj: EQUIPMENT MANAGEMENT PROGRAM

Ref: (a) NAVCOMPTMAN Vol. 3
(b) NAVHOSP29PALMSINST 5540.2A
(c) SECNAVINST 5500.4G
(d) BUMEDINST 4235.7
(e) BUMEDINST 6700.20Q
(f) NAVHOSP29PALMSINST 5420.9A
(g) SECNAVINST 7000.21C
(h) NAVMED P-5132
(i) BUMEDINST 6710.63
(j) Safe Medical Devices Act of 1990

Encl: (l) Equipment Management Manual

1. Purpose. To establish policies and procedures regarding the management and replacement of equipment as required by references (a) through (j).

2. Cancellation. NAVHOSP29PALMSINST 6700.10B.

3. Action. Directorates and Department Heads shall ensure compliance with the provisions of enclosure (l). The Command Equipment Manager shall review enclosure (1) annually or as necessary, and submit changes to the Commanding Officer for approval.

R. S. KAYLER

Distribution:
List A

DEPARTMENT OF THE NAVY
NAVAL HOSPITAL
BOX 788250
MARINE CORPS AIR GROUND COMBAT CENTER
TWENTYNINE PALMS, CALIFORNIA 92278-8250

IN REPLY REFER TO:
NAVHOSP29PALMSINST 6700.10C CH-1
Code 0107
5 August 1997

NAVAL HOSPITAL TWENTYNINE PALMS INSTRUCTION 6700.10C CHANGE TRANSMITTAL 1

From: Commanding Officer

Subj: **EQUIPMENT MANAGEMENT PROGRAM**

Encl: (1) Revised page 1-4 of enclosure (1)

1. **Purpose**. To transmit change 1 to the basic directive.

2. **Action**. Remove page 1-4 of enclosure (1) to the basic directive and replace with enclosure (1).

J. A. NORTON
By direction

Distribution:
List A

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APPENDICES

Enclosure (l)

CHAPTER 1

EQUIPMENT MANAGEMENT

1001. Introduction. Audits and inspections have revealed a need to develop improved procedures to acquire, use, manage, and redistribute equipment at Bureau of Medicine and Surgery (BUMED) managed activities. Many items of equipment are being poorly used, because there are no procedures to identify unneeded or under-utilized items. Equipment may sit idle in clinical services while new procurement requests are generated within the command. Use of equipment pools and periodic "walk-through" inspections can result in more effective utilization of equipment and may eliminate unnecessary new procurement.

1002. Policy. It is the policy of this command to:

a. Identify equipment requirements as early as possible.

b. Plan equipment delivery and installation to avoid delays in availability and minimize disruption of the services provided.

c. Assess total impact of equipment procurement upon the command (e.g., training requirements, personnel requirements, operations and maintenance, Defense Health Program (O&M, DHP) or Military Construction (MILCON) funding for site preparation for construction, etc.).

d. Repair, modify or recondition existing equipment, where feasible and cost effective, instead of new procurement.

e. Use excess equipment available through Department of Defense, federal excess, or surplus listings, when feasible instead of new procurement.

f. Report excess equipment to the Department of Defense, federal excess, and surplus listings.

1003. Definitions

a. Investment Equipment Items (Class 3 Property). Navy-owned equipment having an initial acquisition cost of $100,000 or more.

b. Equipment. Navy-owned personal property meeting the following criteria:

(l) Has an expected normal useful life of one year or more. Enclosure (l)

(2) Is used in performance of the assigned mission.

(3) Is not altered beyond its design capabilities.

(4) Is not consumed in the performance of its work.

(5) Is not an intregal part of a class 2 item (defined in 1003.e.

c. Minor Property Items. Equipment having an initial cost of more than $1,000 but less than $100,000, and with an expected life of one year or more and is not consumed by use.

d. Non-Technical Equipment. All other equipment and furnishings in use at an activity such as, but not limited to, office equipment, food service equipment, refrigerators, freezers, wheelchairs, et cetera.

e. Plant Property. Includes all Navy owned real property and Navy owned personal property of a capital nature in use at activities of the Naval Shore Establishment.

(l) Real property is divided into the following classes:

(a) Plant property, class 1: land

(b) Plant property, class 2: buildings, structures, and utilities.

(2) Personal property (capital and equipment) is divided into the following classes:

(a) Plant property, class 3: equipment other than industrial plant equipment (IPE).

(b) Plant property, class 4: industrial plant equipment.

f. Technical Medical Equipment. Items of equipment used for medical diagnostic or therapeutic purposes: (e.g., X-ray units, electrocardiographs (EKG), electroencephalographs (EEG), electro-surgical units, centrifuges, anesthesia equipment, special function hospital beds, special laboratory equipment, spectro-photometer, cell counters, etc).

g. Audiovisual Equipment and Supplies. Items used for audiovisual purposes: (such as, film, cameras, lenses, flash units, slide projectors, video players, 16mm films, etc.).
Enclosure (l)

1004. Responsibilities

a. The Command Equipment Manager shall:

(l) Be responsible for all phases of the management and ensure internal control of property and equipment at this activity per references (a) and (b).

(2) Maintain the official records of plant property and the official financial plant property records.

(3) Be responsible for the planning, receipt, inventory installation, maintenance, replacement, and disposal of medical or dental equipment.

(4) Assist the Head, Fiscal Department in budgeting, property accounting, reconciling discrepancies, and financial record reporting.

(5) Route each equipment request through the Biomedical Repair Division, Facilities and the Safety Officer for their recommendations.

(6) Maintain a database, by directorate priority, of all equipment requests.

b. Comptroller shall:

(l) Review each equipment request submitted for accuracy and completeness of accounting data and availability of funds.

(2) Plan for funding to meet command equipment needs and advise on the available funding for validated equipment requirements.

c. Board of Directors shall:

(l) Participate fully in the Command's Central Equipment Budget, identifying additional requirements that may occur, before or after, the regular budget submission.

(2) Establish priorities for equipment purchases over $5000 per item.

d. Department Heads shall:

(l) Be responsible and held accountable for all government property under their custody. Equipment will not be

surveyed, transferred, disposed of, or loaned without prior approval of the Command Equipment Manager or Commanding Officer as applicable.

(2) Review and validate property listings on a quarterly basis and during department head turnovers.

(3) Immediately report any equipment received without plant property or minor property identification to the Command Equipment Manager.

(4) Immediately report to Command Equipment Manager any material shipment received directly from vendors.

(5) Request approval to transfer equipment for any reason on a Transfer of Equipment Form (Appendix A).

(6) Immediately report missing, lost, stolen, or damaged property to the Physical Security Officer and Command Equipment Manager, and initiate a Financial Liability/Property Loss Report, DD Form 200.

(7) Designate in writing an Equipment Custodian and an alternate. Forward copy to Command Equipment Manager for insertion into custody card file. Notice will be updated quarterly or within 10 (ten) working days of any changes as applicable. Only the department head or his/her designated representatives are authorized to sign custody cards.

(8) Maintain a file of equipment requests on 29P 1149/1 that have been processed through Fiscal and Material Management.

(9) Purchase equipment under $5000 without prior review by Board of Directors, Equipment Review Committee.

(l0) Submit a 29P 1149/1 to purchase equipment items under $5000 to Materials Management.

(11) Ensure that inhouse inventories are conducted between scheduled quarterly inventories. Monthly is recommended. These will be conducted by the department head's designated representatives. A listing of departmental inventory can be obtained by contacting the Command Equipment Manager.

e. The Physical Security Officer shall:

(l) Investigate losses per reference (c) and provide results of the investigation to the Command Equipment Manager for inclusion with the survey certificate.

(2) Complete Missing, Lost, or Stolen Reports per reference (c).

f. The Head, Personnel Management Department shall ensure that all responsible custodians check in and out with the Command Equipment Manager.

g. The Command Safety Officer is responsible for screening equipment for safety requirements prior to use in the work centers.

h. Staff Members are responsible for the proper care, use, and protection of hospital property.

i. The Director for Administration is designated as the Appointing Authority per SECNAVINST 5500.4G for the Missing, Lost, or Stolen Program, and shall:

(1) Upon review of the DD 200 (Appendix B), determine if the circumstances surrounding the loss or damage of the property require investigation to determine potential personal liability or criminal activity. In the event this occurs, the following procedures shall be followed:

(a) Appoint a Financial Liability Officer by marking block 13 C of the DD Form 200. Individual accountable or responsible for the property being investigated will not be appointed as the Financial Liability Officer.

(b) The Financial Liability Officer conducts and completes the investigation pursuant to reference (c), completes Block 15, and makes recommendations to the Appointing Authority.

(c) The Appointing Authority then makes recommendations to the Approving Authority (Executive Officer) regarding the need to hold an individual liable financially for the loss, or to relieve them of the responsibility for accountability of the loss.

j. The Executive Officer is appointed as the Approving Authority for DD Form 200s. As such, he/she will make determinations to either relieve involved individuals from responsibility and/or accountability or approve assessment of financial liability.

k. Head Facilities Management Department shall screen applicable equipment requests to ensure available power, water and space, are available to support the equipment.

l. Environmental Health Officer and Industrial Hygiene Officer will inspect all surveyed medical equipment for biological and hazardous chemical contaminants.

1005. The Survey Board. In the event that the Surveying Officer's final action is not approved by the Reviewing/Appointing Authority, a Survey Board shall be appointed by the Commanding Officer for the purpose of conducting a more thorough review. The board shall consist of two or more commissioned officers. The individual charged with the custody of the property in question may not be a board member.

a. Responsibilities of the Board:

(l) Review previous reports.

(2) Conduct its own investigation.

(3) Submit report and recommendation to the Commanding Officer.

b. Final Action. The Commanding Officer shall take final action on the results and recommendations of the board, except when the property value or cost of repair exceeds $10,000, or he/she is personally responsible for the property in question. In such instances, the case shall be referred to the next higher level in the chain of command.

1006. Equipment Inventories

a. Policy. All records of plant and minor equipment shall be maintained both on a quantitative and monetary basis. Additionally, a reconciliation of property records and equipment shall be completed at least semi-annually.

b. Semi-Annual Inventories

(l) Inventories are held semi-annually in September and March.

(2) The Command Equipment Manager (CEM) shall:

(a) Validate property values in order to classify and record the appropriate equipment category. Equipment categories are either classified as plant property or minor property (plant property over $100,000; minor property under $100,000.

(b) Provide a mechanized listing of both plant and minor property, by location, to each department head for verification, additions, and deletions.

(3) Department Heads shall:

(a) Verify that the plant property or minor equipment is actually located in their department.

(b) Match the plant property or minor property number to existing equipment.

(c) Verify the serial number and the description of equipment.

(d) Ensure that property numbers are readily visible, identifiable, and easily readable.

(e) Annotate legibly on each property listing any equipment which was not identified to include the following information:

1 Plant or minor property number.

2 Item nomenclature and description.

3 Manufacturer and model number.

4 Manufacturer's serial number.

5 Current location.

(f) Items identified as additional to the department inventory shall be added to that inventory.

(g) A clean and final copy of the inventory will be forwarded to each department upon completion of the entire command inventory. Department Heads will sign and date the inventory listings and return a copy with accompanying documentation to Command Equipment Manager. If equipment cannot be located in the facility, the Department Head will complete a DD Form 200 within 30 days after completion of the inventory.

(4) The Command Equipment Manager will update the automated inventory listing to reflect additions, corrections, and transfers.

(5) Missing, Lost or Stolen Equipment

(a) Missing, lost or stolen equipment must be immediately reported to the Command Equipment Manager and the Physical Security Officer.

(b) The Command Equipment Manager will request all departments to search for the missing equipment. In the event the item is not located, the DD Form 200 will be submitted to the Director for Administration for further action.

c. Triennial Inventory

(l) The Command Equipment Manager is responsible for conducting the triennial inventory of plant property per reference (a).

(2) Inventories shall be conducted and completed within the time set forth in the inventory schedule. "Initial Inventory Year" schedule began 1 July 1991 and was completed 31 March 1992. The triennial inventories will continue on a similar three year cycle.

(3) Responsibilities

(a) The Board of Directors shall assign inventory team members under the direction of the Command Equipment Manager. There will be a minimum of two teams consisting of two members on each team.

(b) The Command Equipment Manager shall:

1 Assign specific inventory areas, including target dates.

2 Train personnel in taking inventory.

(c) Physical Inventory Teams shall:

1 Be responsible for sighting and recording all major equipment.

2 Identify the equipment by USN plant property number, serial number, nomenclature, and location. Note: If USN is not identified on equipment, affix "USN" by stencil or etching.

3 Confirm that the plant property listing is accurate by annotating additions, deletions, or corrections. Additions will include the following information: Plant property number, Federal Supply number, preventive maintenance (medical equipment) number, item description, serial number, and estimated value.

4 Notify the Command Equipment Manager if a plant property item cannot be identified by USN plant number. The Command equipment Manager will research the item for identification purposes and provide the inventory team with guidance for attaching the correct property number.

5 Upon completion of a departmental inventory, the inventory team shall obtain the Department Head's signature attesting to the fact that the inventory was done, is valid, and that they accept responsibility for the inventory as annotated.

6 Inform the Department Head, the Command Equipment Manager, and the Physical Security Officer of any item(s) missing.

(d) Inventory Team Reports shall:

1 Include team names, area inventory, findings, two (2) copies of the plant property listing with additions, corrections, or deletions, rough DD Form 1342s for "Gain by Inventory."

2 Be submitted for each area inventoried.

d. "Walk-through Inspections" shall be conducted as needed by an inspection team consisting of:

(l) One Commissioned Officer.

(2) The accountable Department Head.

(3) Leading Petty Officer, Medical Repair.

(4) A Recorder.

e. A written report shall be provided to the Command Equipment Manager within five working days of the inspection on the current status of equipment. Negative reports are required.

1007. Screening. All requests for procuring equipment will be screened against on-hand assets and excess or surplus listings maintained by the Command Equipment Manager. Purchase requests for medical equipment over $1000 shall be reviewed by Medical Repair Division for compatibility.

1008. Disposal and Survey of Equipment

a. If equipment items are worn, obsolete, or excess to the needs of the using department, the Department Head will submit a Report of Survey (APPENDIX C) to the Environmental Health Officer and Industrial Hygiene Officer. These personnel will inspect all surveyed equipment for biological and hazardous chemical contaminants and certify such on the Report of Survey. No equipment will be accepted without these signatures. The Report

of Survey will then be forwarded to the Equipment Manager who will determine if the equipment item (minor or plant property) should be redistributed within the command; turned over to the Defense Reutilization and Marketing Office (DRMO); or redistributed by the direction of Naval Medical Logistics Command.

(1) The Department Head is responsible for completing blocks (1) through (11) of the Report of Survey. The Report of Survey will then forwarding it to the Equipment Manager for further disposition.

(2) The Command Equipment Manager will verify the information and annotate the property record.

(3) All medical and non-medical equipment must be condition coded by a Biomedical Equipment Repair Technician (BMET). The condition code must be attached to the equipment item before it is forwarded to DRMO.

(4) Director for Administration then makes a determination on whether a formal Survey Board is warranted before signing block (13), authorizing disposition by Material Management.

b. Equipment will not be picked up or accepted for survey turn-in until a Report of Survey is completed.

1009. Storage of Equipment

a. Equipment which is temporarily excess to the daily needs of a department, but will be needed in the future may, with the concurrence of the Head, Material Management Department, be stored in the Material Management Department.

b. Requests for storing equipment will be initiated by memorandum. Requests shall include the property number, the make and model of the equipment stored, the reason the item is to be stored, estimated length of time equipment is to be stored, and any peculiar storage requirements (such as size restrictions, climate control etc.).

c. All medical equipment to be stored will be inspected by the Medical Repair Division to ensure that equipment is properly prepared for storage and to provide a condition code.

d. A copy of the Transfer of Equipment Form (Appendix A) will be forwarded by the accountable Department Head to the Command Equipment Manager when the item is placed in storage. Upon receipt of this copy, the Command Equipment Manager will change the location code for that equipment to reflect its storage location.

e. Any equipment not intended for contingency purposes that is stored in excess of 180 days or not claimed after expiration date will be considered for redistribution. The Department Head will be contacted to initiate a Report of Survey. Recall of stored equipment requires 24 hours notice, except in emergencies.

1010. Transfer of Equipment

a. When a department requires equipment which is in the custody of another department, a memorandum (Appendix A) shall be submitted to the Command Equipment Manager for approval and inventory transfer.

b. Medical equipment may be loaned or transferred to other military activities or naval vessels in an emergency at the discretion of the Commanding Officer by utilizing Appendix D.

c. Equipment will not be removed from the command without the Commanding Officer’s approval.

1011. Equipment Identification. Department Heads will ensure that each equipment item is properly identified with either command identification tag, stencil or etching. Equipment items not properly identified will be reported to the Command Equipment Manager.

1012. Loan of Government Property

a. Government property loaned to staff or other commands requires a memorandum (Appendix E) from the requesting department Head to the Command Equipment Manager. Persons requesting loans will hand carry the memorandum to the Command Equipment Manager. Once the memorandum has been received, a Naval Hospital Loan Agreement (Appendix F) will be completed by the Command Equipment Manager.

b. Home loan equipment agreements will be completed by the Discharge Planner and forwarded to Materials Management for issue to the patient.

c. Government property will not be loaned without the agreement being fully effected by all concerned. It is emphasized that Department Heads are fully responsible for government property under their cognizance and for following the correct procedure for loan of that property.

d. All loans of government property will be directed by the Material Management Department, Monday through Friday between the hours of 0800 and 1600.

1013. Property Management and Budgeting System (PMBS)

a. The equipment inventory is automated through the use of the PMBS. The Equipment Manager is responsible for the maintenance and accuracy of the PMBS database.

b. All equipment will be assigned a barcode and a plant or minor property control number.

c. Equipment data shall be entered into PMBS prior to the equipment being placed into service.

Chapter 2

EQUIPMENT REPLACEMENT

2001. Replacement Program Investment Equipment

a. References (d) and (e) require every command to develop and maintain a formal equipment replacement program. A minimum program shall include the following:

(l)An Equipment Review Committee, under the auspices of the Board of Directors (BOD), which shall meet as directed by reference (f). The BOD shall develop the Command's investment equipment budgets or additional requirements after the budget submission and shall establish a priority for each item of equipment over $5000.

(2) A continuing documented review of the age and physical condition of each item of equipment will be conducted. This action will assist in determining if an item should or should not be replaced. Reference (e) contains a guide to use in determining the normal life expectancy of many items of equipment. However, it should only be used as a guide since the condition and usage of the item will aid in determining if it should be replaced.

(3) A formal preventive maintenance program as detailed in reference (e), to include condition coding of each piece of equipment in the facility.

(4) Maintenance of an auditable record of investment equipment requirements, both replacement and new acquisitions.

(a) Current Year. The fiscal year currently in progress (e.g., the current year as of the date of this instruction is Fiscal Year 1996).

(b) Apportionment Year. The fiscal year following the current year (e.g., in FY-96 the apportionment year is FY-97).

(c) Budget Year. The fiscal year two years following the apportionment year (e.g., in apportionment year FY-97 the budget year is FY-98). This budget provides BUMED Program Objective Memorandums (POM) requirements.

b. All investment equipment requirements will be documented on the Command Equipment Request, NAVMED 6700/12 contained in Appendix G.

2002. Replacement Program Equipment $5000 to $100,000

a. Equipment over $5000 but under $100,000 will be requested on a DD Form 1149 and a Minor Equipment Information Supplement, NH29P 6700/14 (Appendix H) and submitted to the Command Equipment Manager.

b. The Command Equipment Manager will prepare a listing of all equipment requests for review by the Board of Directors.

c. The BOD will review all equipment requests for items over $5000 and forward their recommendations to the Commanding Officer for approval or disapproval. Department Heads will be notified by the Commanding Officer's endorsement of the minutes.

2003. Replacement Program Equipment Under $5000. Equipment items under $5000 require Department Head approval and are reviewed by the Command Equipment Manager to ensure that the equipment is not unnecessarily duplicated, and is compatible with existing equipment.

2004. Approval Required Prior to Procurement

a. Equipment Requiring Bureau of Medicine and Surgery (BUMED) Approval.

(1) All investment equipment items over $100,000 must be approved by BUMED prior to procurement. References (e) and (f) provide the guidance required to seek approval.

(2) Restricted Equipment Items, which include the following:

(a) Clinical Investigation Program or Radiation Health Specialty Equipment.

(b) Automated Data Processing (ADP) Equipment.

(c) Navy Occupational Safety and Health Program Support Equipment.

b. Equipment leasing. Pursuant to references (e), (g) and (h) requests for lease, or lease renewals, of equipment must include an economic analysis comparing costs of lease versus purchase. The Material Management department and the requesting department will prepare this analysis in the format prescribed in reference (g) and submit it to the Command Equipment Manager.

Chapter 3

SAFE MEDICAL DEVICES REPORTING

3001. Medical Device Reporting for User Facilities

a. References (i) and (j) require every command to report all medical device problems. A minimum program shall include:

(l) The Equipment Manager will be designated as the Command Safe Medical Devices Representative and will serve as the contact person with the Defense Personnel Support Center (DPSC). The DPSC is the Department of Defense clearing house and central contact point with the Food and Drug Administration (FDA). The contact person is to be an employee of the facility; however, the facility and its officials have the ultimate responsibility for compliance with the requirements.

(2) Implementation and maintenance of written procedures for the following areas:

(a) Training and education programs which focus on employee responsibilities, including how to identify and report events that may be subject to reporting. The Equipment Manager will conduct these classes.

(b) Internal systems that provide for identification, communication, and evaluation of events that may be subject to reporting. These systems should also include a standardized review procedure (to include the Safety Officer) for determining when an event meets the criteria for reporting and mechanisms to assure the timely transmission of complete reports.

(c) Documentation and record keeping requirements for:

1 Incident information that was reviewed.

2 All reports and information submitted to the FDA and manufacturers.

3 Information that facilitates the submission of semi-annual reports.

4 Systems that ensure access to information that facilitates timely follow-up and inspection by DPSC and FDA.

3002. Submission of Reports

a. The Command Safe Medical Devices Representative must report medical device related deaths directly to DPSC, FDA and manufacturer, if known, via an SF-380. Reports of serious illnesses and injuries that are device related must be reported directly to the manufacturer. If the manufacturer is not known, the report will go directly to DPSC. DPSC expects user facilities to make a reasonable effort to identify the manufacturer of a device involved in a reportable event if it is not immediately known.

b. Reports will be sent to DPSC at the following address:

Defense Personnel Support Center
QA Branch
Technical Operations Division
2800 South 20th Street
Philadelphia, PA 19145-5099

c. Reports submitted to the FDA shall be addressed as:

Food and Drug Administration
Center for Devices and Radiological Health
MDR User Report
P.O. Box 3002
Rockville, MD 20847-3002

d. All inquiries about reporting should be mailed to:

Food and Drug Administration
Center for Devices and Radiological Health
Division of Product Surveillance (HFZ-340)
Medical Device Reporting Inquiries
1390 Piccard Drive
Rockville, MD 20850

e. Appendix I is the form for reporting safe medical device deficiencies using the codes provided in Appendix J.

3003. Reportable Events

a. A Medical Device Reporting (MDR) event refers to an event for which a person has received or became aware of information that reasonably suggests that there is a probability that a device has caused or contributed to a death, serious injury, or serious illness.

b. An MDR reportable event includes the failure of a diagnostic device if information reasonably suggests that there is a probability that a misdiagnosis or lack of diagnosis resulted from the failure:

(l) Has caused or contributed to a death, serious injury, or serious illness, or

(2) Would cause or contribute to a death, serious illness or serious injury if it were to recur.

c. MDR reportable events also include events that are similar or identical to previously reported events. Reportable events caused by user errors or the failure to service or maintain devices must also be sent to manufacturers or the FDA, depending upon the event.

d. All personnel are responsible for reporting MDR events to the designated Safe Medical Safe Devices Representative when they receive or become aware of information that reasonably suggests that a reportable event has occurred. Medical personnel are deemed to "become aware" of a reportable event when they have sufficient information to make a determination that a report is required.

e. If a biomedical device does not perform as advertised or malfunctions, Biomedical Repair will notify the Command Safe Medical Device Representative.

3004. Death, Serious Injury and Illness Reporting Time Frame.

a. When the Command has made a decision that the death, serious injury, or illness is a reportable event, the report must be submitted within ten (10) working days.

APPENDIX A
TRANSFER OF EQUIPMENT

From:
To: Command Equipment Manager

Subj: TRANSFER OF EQUIPMENT

Ref: (a) NAVHOSP29PALMSINST 6700.10B

1. Pursuant to reference (a), the following equipment:

    a. Item_____

    b. Manufacturer_____

    c. Model _____

    d. property account number/minor property number
    _____

    e. Serial number _____

is being transferred to:

_____ as of _____

for the purpose of _____

_____
Signature of releasing Department Head

_____
Signature of accepting Department Head

APPROVED/disapproved

_____
Command Equipment Manager

Copy to:
Medical repair Division

NH29P 6700/12 (REV. 3-92)

APPENDIX B

FINANCIAL LIABILITY INVESTIGATION OF PROPERTY LOSS

PRIVACY ACT STATEMENT

AUTHORITY: 10 USC 136; 10 USC 2775; DoD Instruction 7200.10; EO 9397.

PRINCIPAL PURPOSE: To officially report the facts and circumstances supporting the assessment of financial charges for the loss, damage, or destruction of DoD-controlled property. The purpose of soliciting the SSN is for positive identification.

ROUTINE USES: None.

DISCLOSURE: Voluntary; however, refusal to explain the circumstances under which the property was lost, damaged, or destroyed may be considered with other factors in determining if an individual will be held financially liable.

1. DATE INITIATED (YYMMDD)	2. INQUIRY/INVESTIGATION NUMBER	3. DATE LOSS DISCOVERED (YYMMDD)

4. NATIONAL STOCK NO.	5. ITEM DESCRIPTION	6. QUANTITY	7. UNIT COST	8. TOTAL COST

9. CIRCUMSTANCES UNDER WHICH PROPERTY WAS (X one) (Attach additional pages as necessary) ☐ LOST ☐ DAMAGED ☐ DESTROYED

10. ACTIONS TAKEN TO CORRECT CIRCUMSTANCES REPORTED IN BLOCK 9 AND PREVENT FUTURE OCCURRENCES (Attach additional pages as necessary)

11. INDIVIDUAL COMPLETING BLOCKS 1 THROUGH 10

a. ORGANIZATIONAL ADDRESS (Unit Designation, Office Symbol, Base, State/Country, Zip Code)	b. TYPED NAME (Last, First, Middle Initial)	c. AUTOVON/DSN NUMBER
	d. SIGNATURE	e. DATE SIGNED

12. (X one) ☐ RESPONSIBLE OFFICER (PROPERTY RECORD ITEMS) ☐ REVIEWING AUTHORITY (SUPPLY SYSTEM STOCKS)

a. NEGLIGENCE OR ABUSE EVIDENT/SUSPECTED (X one) ☐ (1) Yes ☐ (2) No	b. COMMENTS/RECOMMENDATIONS

c. ORGANIZATIONAL ADDRESS (Unit Designation, Office Symbol, Base, State/Country, Zip Code)	d. TYPED NAME (Last, First, Middle Initial)	e. AUTOVON/DSN NUMBER
	f. SIGNATURE	g. DATE SIGNED

13. APPOINTING AUTHORITY

a. RECOMMENDATION (X one) ☐ (1) Approve ☐ (2) Disapprove	b. COMMENTS/RATIONALE	c. FINANCIAL LIABILITY OFFICER APPOINTED (X one) ☐ (1) Yes ☐ (2) No

d. ORGANIZATIONAL ADDRESS (Unit Designation, Office Symbol, Base, State/Country, Zip Code)	e. TYPED NAME (Last, First, Middle Initial)	f. AUTOVON/DSN NUMBER
	g. SIGNATURE	h. DATE SIGNED

14. APPROVING AUTHORITY

a. ACTION (X one) ☐ (1) Approve ☐ (2) Disapprove	b. COMMENTS/RATIONALE	c. LEGAL REVIEW COMPLETED IF REQUIRED (X one) ☐ (1) Yes ☐ (2) No

d. ORGANIZATIONAL ADDRESS (Unit Designation, Office Symbol, Base, State/Country, Zip Code)	e. TYPED NAME (Last, First, Middle Initial)	f. AUTOVON/DSN NUMBER
	g. SIGNATURE	h. DATE SIGNED

DD Form 200, FEB 91 Previous editions are obsolete. S/N 0102-LF-011-9100

APPENDIX B

15. FINANCIAL LIABILITY OFFICER			
a. FINDINGS AND RECOMMENDATIONS (Attach additional pages as necessary)			
b. DOLLAR AMOUNT OF LOSS	c. MONTHLY BASIC PAY	d. RECOMMENDED FINANCIAL LIABILITY	
e. ORGANIZATIONAL ADDRESS (Unit Designation, Office Symbol, Base, State/Country, Zip Code)	f. TYPED NAME (Last, First, Middle Initial)		g. AUTOVON/DSN NUMBER
	h. DATE REPORT SUBMITTED TO APPOINTING AUTHORITY (YYMMDD)		i. DATE APPOINTED (YYMMDD)
	j. SIGNATURE		k. DATE SIGNED

16. INDIVIDUAL CHARGED			
a. I HAVE EXAMINED THE FINDINGS AND RECOMMENDATIONS OF THE FINANCIAL LIABILITY OFFICER AND (X one)			
(1) Submit the attached statement of objection.		(2) Do not intend to make such a statement.	
b. I HAVE BEEN INFORMED OF MY RIGHT TO LEGAL ADVICE. MY SIGNATURE IS NOT AN ADMISSION OF LIABILITY.			
c. ORGANIZATIONAL ADDRESS (Unit Designation, Office Symbol, Base, State/Country, Zip Code)	d. TYPED NAME (Last, First, Middle Initial)		e. SOCIAL SECURITY NUMBER
	g. SIGNATURE		h. DATE SIGNED
f. AUTOVON/DSN NUMBER			

17. ACCOUNTABLE OFFICER			
a. DOCUMENT NUMBER(S) USED TO ADJUST PROPERTY RECORD			
b. ORGANIZATIONAL ADDRESS (Unit Designation, Office Symbol, Base, State/Country, Zip Code)	c. TYPED NAME (Last, First, Middle Initial)		d. AUTOVON/DSN NUMBER
	e. SIGNATURE		f. DATE SIGNED

DD Form 200 (Back), FEB 91

Appendix B
to Enclosure (1)

REPORT OF SURVEY

This form is to be used for the purpose of surveying equipment only. It is not intended to be used as an MLSR DD Form 200. All hospital units that have equipment to be surveyed will use this form. If the equipment is missing , lost or stolen, the Operating Management Department may be contacted and the DD Form 200 that covers missing, lost or stolen equipment may be obtained.

1. REPORT OF SURVEY

2. SURVEY NUMBER

3. JULIAN DATE

4. NATIONAL STOCK NO.	5. ITEM DESCRIPTION NOMENLATURE: MFG: MOD#: SER#: PLANT AOCT/MP# PM#: BAROODE#:	6. QUANTITY	7. UNIT COST	8. TOTAL COST

9. REASON FOR SURVEY:

THIS EQUIPMENT HAS BEEN CLEANED, SANITIZED AND IS FREE OF ALL CHEMICAL AND BIO-HAZARDOUS WASTE.

DEPARTMENT HEADS SIGNATURE: _____
PRINTED NAME:
GRADE:
TITLE:

MEDICAL EQUIPMENT WILL **NOT** BE ACCEPTED WITHOUT THE ABOVE INFORMATION.

CONDITION CODE _____ BMET'S SIGNATURE_____

10. INDIVIDUAL INITIATING SURVEY

a. TYPED NAME (Last, First, Middle Initials)	b. SIGNATURE	c. DATE SIGNED	D. DSN NUMBER

11. RESPONSIBLE OFFICER

a. ORGANIZATIONAL ADDRESS (COMPLETE)	b. TYPED NAME (Last, First, Middle Initial)	c. DNS NUMBER
	d. SIGNATURE	d. DATE SIGNED

12. ACCOUNTING OFFICER

a. ORGANIZATIONAL ADDRESS (COMPLETE)	b. TYPED NAME (Last, First, Middle Initial)	c. DSN NUMBER
	d. SIGNATURE	d. DATE SIGNATURE

APPROVING OFFICIAL

	APPROVED	a. COMMENTS
	DISAPPROVED	

b. ORGANIZATIONAL ADDRESS (COMPLETE)	c. TYPED NAME (Last, First, Middle initial)	d. DSN NUMBER
	d. SIGNATURE	f. DATE SIGNED

SHIPPING CONTAINER TALLY → 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50

REQUISITION AND INVOICE / SHIPPING DOCUMENT

Form Approved
OMB No. 0704-0246

1. FROM: *(Include ZIP Code)*
DEPT: POC:
NOMENCLATURE: EXT:
NAVAL HOSPITAL TWENTYNINE PALMS UIC: 35949

2. TO: *(Include ZIP Code)*
EQUIPMENT MANAGER
NAVAL HOSPITAL TWENTYNINE PALMS, CA
(MATERIAL MANAGEMENT DEPARTMENT)

3. SHIP TO - MARK FOR
DEPT:
GAINING COMMAND:
UIC:

SHEET NO.	NO. OF SHEETS	5. REQUISITION DATE	6. REQUISITION NUMBER

7. DATE MATERIAL REQUIRED *(YYMMDD)*	8. PRIORITY

9. AUTHORITY OR PURPOSE

10. SIGNATURE	11a. VOUCHER NUMBER & DATE *(YYMMDD)*

12. DATE SHIPPED *(YYMMDD)*	b.

13. MODE OF SHIPMENT	14. BILL OF LADING NUMBER

15. AIR MOVEMENT DESIGNATOR OR PORT REFERENCE NO.

4. APPROPRIATIONS SYMBOL AND SUBHEAD	OBJ. CL.	BUR. CONT. NO.	SUBAL-LOT.	AUTHORIZATION ACCT'G ACTIVITY	TRANS. TYPE	PROPERTY ACCT'G ACTIVITY	COUN-TRY	COST CODE	AMOUNT

ITEM NO. (a)	FEDERAL STOCK NUMBER, DESCRIPTION, AND CODING OF MATERIAL AND / OR SERVICES (b)	UNIT OF ISSUE (c)	QUANTITY REQUESTED (d)	SUPPLY ACTION (e)	TYPE CON-TAINER (f)	CON-TAINER NOS. (g)	UNIT PRICE (h)	TOTAL COST (i)
	EQUIPMENT CLASS: NOMENCLATURE MANUFACTURER: MODEL: SERIAL# PROPERTY ACCOUNT: (TRANSFER OF CUSTODY) RECEIVED BY:							

16. TRANSPORTATION VIA MATS OR MSTS CHARGEABLE TO

17. SPECIAL HANDLING

18. RECAPITULATION OF SHIPMENT

ISSUED BY	TOTAL CON-TAINERS	TYPE CON-TAINER	DESCRIPTION	TOTAL WEIGHT	TOTAL CUBE
CHECKED BY					
PACKED BY					
			← TOTAL →		

19. RECEIPT

	DATE *(YYMMDD)*	BY	
CONTAINERS RECEIVED EXCEPT AS NOTED			SHEET TOTAL
QUANTITIES RECEIVED EXCEPT AS NOTED	DATE *(YYMMDD)*	BY	GRAND TOTAL
POSTED	DATE *(YYMMDD)*	BY	20. RECEIVER'S VOUCHER NO.

DD Form 1149, DEC 93
306/080

51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100

Previous editions are obsolete.

S/N 0102-LF-017-7900

(Navy Overprint 1994)

APPENDIX E
LOAN OF GOVERNMENT EQUIPMENT

Date:

From: Head, _____
To: Command Equipment Manager

Subj: LOAN OF GOVERNMENT PROPERTY

Ref: (a) NAVHOSP29PALMSINST 6700.10B

1. It is requested that the following government property:

    a. Item:

    b. Plant Property Number/Minor Property Number:

    c. Serial Number:

be loaned to:

    a. Name:

    b. Home Address: Home Phone:

    c. Organization: Work Phone:

    d. Supervisor: Work Phone:

for the purpose of:_____

_____

_____
(Department Head Signature)

NH29P 6700/11 (3-92)

APPENDIX F
EQUIPMENT LOAN AGREEMENT

1. This is an agreement of loan between Naval Hospital, Twentynine Palms and _____ as prescribed by NAVHOSP29PALMSINST 6700.10B.

2. The purpose for this loan is _____ to _____ (not to exceed 90 days).

4. The property to be loaned is:

Description:

Manufacturer: Model:

Serial Number: Property Number:

Preventive Maintenance Number:

Condition Code: Value:

5. I, the undersigned, understand the title and ownership of the property described will remain within the department of the Navy, Naval Hospital, Twentynine Palms, California.

6. I, the undersigned, do accept the obligation to protect all proprietary, patent, and industrial rights in the property, the information furnished with the property, and the information derived from it.

7. I, the undersigned, will assume all liabilities, responsibilities, and cost incurred incident to the loan of property, such as the removal of the material from storage, crating, handling, packing, transportation, activation, conversion, operation, repair, return, and replacement of material in storage.

8. I, the undersigned, assume all risk of loss or damage and will return the property in as good condition as when loaned, reasonable wear and tear accepted, and that expense of placing it in such a condition will be my responsibility.

NH29P 6700/13 (3-092)

9. I, the undersigned, understand that in case of emergency or when it is determined to be in the best interest of the Government, Naval Hospital reserves the right to revoke all or part of this agreement.

10. I will indemnify the Government for all third party liability arising in connection with the property during the period of the loan.

Name: SSN: Date:

Organization: Work Phone:

Home Address: Home Phone:

Command Equipment Manager: Date:

Borrower’s Signature:

COMPLETE ONLY AFTER ITEM HAS BEEN RETURNED

Date of Return:

Borrower’s Signature:

Command Equipment Manager:

Date returned to Lending department:

Department Heads Signature:

NH29P 6700/13 (3-92)

EQUIPMENT REQUEST UIC-ECN:

4. Equipment is___New____Expansion____Replacement____Upgrade If replacement/upgrade,complete the following:
a. Item being replaced/upgraded Nomemclature:_____Manuf:_____
Model No:_____ Serial No:_____ Plant Acc#_____
b. Proposed disposition of replaced item: ___Dispose___Excess___Retain
Why retain?:_____

5. Requesting Department Head
_____
Typed name/signature Phone no.

6. Is ASDP required?__Yes(attach copy)__No
_____
Typed name/signature of Head, MID Date

7. Facilities Manager:
a. Is facility modification required (ie: additional electrical support, plumbing, emergency power, gas, exhaust, additional heating, A/C, ventilation, radiation shielding)?
_____ Yes _____No (If yes, estimated Cost)$_____
b. Is installation required? ___ Yes ___ No (If yes, estimated cost)$_____
c. Are M2/R2 dollars required for installation? ___ Yes ___ No(If yes, are the available)__Yes __No
d. Are there any environmental impacts due to the proposed request (ie: more hazardous waste generated, increased noise levels, radiation, ozone depleting substances)?
e. Additional considerations not previously mentioned.
_____
Typed name/signature of Facilities Manager Phone no.

8. Biomedical Engineering Representative:
a. Maintenance/repairs will be provided by:
_____In/house BMET (Is additional training required)? _____Yes _____No
_____Commercial contract (Estimated Cost)$_____
b. Complete for replaced equip: Month/Yr installed_____Life expectancy_____ Cond Code____
Total manhours expended: Preventive Maint:_____Corrective Maint:_____
Cost of repair parts/service to date:$_____Cost of Maint service to date$_____
Is maintenance record (NAVMED 6700/3 or BIOFACS) attached____Yes_____Not available
_____
Typed name/signature of Biomedical Engineering Representative Phone No.

9. Are there any OSHA requirments?___Yes___No
If yes, attach addendum (P-5132, Annex 4)
_____
Typed name/signature of Safety Officer Date

10. Reviewed by Equipment Review Committee
_____
Typed name/signature of Chairman Date

11. Type of funding ___OP___FIP___IH___Lease
___Collateral___O&M
_____
Typed name/signature of Comptroller Date
_____
Typed name/signature of Equipment Mgr Date

12. Commanding Officer:
_____
Typed name/signature Date
---
13. HSO,NEHS, or HSETC Review
_____
Typed name/signature of reviewer Date

NAVMED 6700/12 (12/89)

Appendix G
to Enclosure (l)

APPENDIX G

EQUIPMENT REQUEST		
1. Medical Facility (Name and City): Requesting Dept: Standard Nomenclature:	UIC: Branch UIC: Dept Code:	ECN: DATE: Command Priority: Equip Type Code:

2. ITEM DESCRIPTION (How the equipment will be used with general description and characteristics including ALL components and accessories)

Suggested Manufacturer: Model No: Acq Cost:

3. JUSTIFICATION:

a. How is the function of the requested item currently being accomplished:

b. Impact of acquiring requested item. (Affect on CHAMPUS, workload, efficiency, productivity, manpower, cost reduction, maintenance, etc. include increases and decreases):

c. What similar equipment is available in YOUR FACILITY and how many hours per day is it used?:

d. Will requested item be used in conjunction with other equipment (existing or programmed?:

e. Impact if item is not funded in the Fiscal Year requested:

f. Cost to rehabilitate old equipment: $_____

g. Is this item in support of Occupational Health functions?_____Yes_____No

h. Is training required?: _____Yes _____No (If yes, has O&M funding been identified?)

Equipment Request

Medical Facility Naval Hospital 29 Palms		
Dept/Div:	Biomedical Engineering	UIC:35949
Date prepared	Standard Nomenclature:	

1. Essential Characteristics:(detailed, nontechnical, functional description, including accessories and options. Minimum features and capabilities required to perform the intended task. DO NOT use manufacturer's model number, catalogue numbers or proprietary information. Must be generic, not manufacturer specific)

Is this equipment a replacement item No Yes, PM# of existing unit

JUSTIFICATION:

How is the function currently being accomplished? (Champus, TAD/Referral to camp Pendleton, ETC)

Impact of acquiring equipment? (Affect on Champus, workload, productivity, cost reduction, Maintenance, etc.. Include increases and decreases)
.

2. General design features required to meet existing installation limitations: **N/A**

a. Maximun dimensions in inches: Height Width Depth
b.Weight not to exceed (in pounds)
c. Electrical Voltage requirements VAC Hz Amp Phase
d. Mounting Requirements: (Seismic, Fastened to floor, ceiling, deck)
e. Right or left hand operation:
f. Other unique requirements (surge protectors, Locks, Doors, etc)

3. Installation Requirements: (circle as appropriate)

a. No installation Required

b. Government installed. All installation and site preparation will be completed by the government. Contractor will furnish installation instructions/site preparation requirements within 10 days of award of contract.

c. Contractor installed. Price of installation will be included in contract.

(1) Contractor will provide plans for required facility modification/site preparation within 10 days of award of contract.

(2) on site pre bid (offer) visit required. Contractor will schedule a site visit within 15 days of solicitation due date. Date site will be available is ___.

(3) Scale drawing of installation site attached.

Installation requirements approved:

Biomedical Engineering Department **Facilities Management**

4. Training:

a. No operator training required.

b. Training Required.

Operator/User: Number of trainees.

Location of training: On site Manufacturers site

5. Is the ability of the manufacturer to provide local maintenance and support Critical?
NO ___ yes ___ hours per day ___ days per week. Repair and parts ___ Preventive Maintenance only ___

6. Shipping Instructions:

a. Ship to Address: NAVAL HOSPITAL 29 PALMS

b. Special handling instructions:

c. Required delivery date:

7. Known acceptable sources of supply: (Attach Manufacturers literature and a complete list of components, parts, options)

Source #1 Example
ERBE USA 404-349-0900
3800 camp creek Pkwy
Atlanta GA 30331

a. Model APM 600, with Extension Board and Test Box 2

Source #2 BIOTEK 800-451-5172

Source #3 Dynatech Nevada 800-648-7952

8. Any other sources found to be acceptable: (Continue block 7)

9. **Unacceptable companies** reviewed and why unacceptable: (incompatible with existing equipment, does not meet resolution standards, etc...)

10. Sole source procurement required? (If yes, complete sole source justification)

11. Does this equipment require an ASDP? (If yes, consult MID for justification)

12. Biomedical Engineering Requirements:

Test equipment required to support equipment:

2 Operator manuals
2 Service Manuals
Can the existing unit be refurbished? Cost $

Service/Maintenance Training Requirements: Number of trainees Cost $

13. Signatures of approval: (typed name and signature are required)

Originator Phone # Date

Head, Biomedical Engineering Phone # Date

Head, Facilities Management Department Phone # Date

Equipment Manager/Supply Officer Phone # Date

APPENDIX I

MEDICAL DEVICE REPORTING TEST FORM

MEDICAL DEVICE REPORTING USER FACILITY REPORT NUMBER

_____

HFCA No. Year Sequence No.

PART 1

TEST FORM

1. User Facility (or Distributor) Name_____

2. User facility (or Distributor) Zip Code_____

3. Type of Submission _____A- Original Submission
B- Response to FDA Request

DEVICE IDENTIFICATION

C- Correction of Submission
D- Additional Information

4. Manufacturer Name_____

5. Brand Name_____

6. Generic Product Name_____

7. Model Number_____

8. Catalog Number_____

9. Other ID Number_____

10. Serial Number_____

11. Lot Number_____

12. Device Expiration Date MM/YY ____

13. Device Purchase Date MM/YY ____

14. Device Labeled for Single Use (Y or N) ___

15. Implanted Device (Y or N) ____

16. If yes, Device Implant Date MM/DD/YY _____

PATIENT INFORMATION

17. Age ___years (or ___months) 18. Sex (M or F) ___

19. Medical Status prior to Event (see codes) ____

20. Multi-Patient Involvement (Y or N) ____

2l. If yes - How many Patients were involved ____
Include Above Details for Each Patient in Attached Narrative

DEVICE MAINTENANCE AND SERVICE INFORMATION

22. Serviced in Accordance With Service Schedule (Y or N) ___

23. Last Date devices Was Serviced MM/YY ____

24. Service performed By (see codes) ____

25. Service Documentation / History Available (Y or N) ____

EVENT INFORMATION

26. Type of Adverse Event (D,IN,IL,M) ____

27. Imminent Hazard to Public Health (Y or N) ___

28. Date of Event MM/DD/YY _____

29. Date Medical personnel Became Aware of Event MM/DD/YY _____

30. Date Event Was Reported to Manufacturer MM/DD/YY _____

3l. Was Device Used as Labeled and Intended (Y or N) _____

32. Who Was Operating Device When Event Occurred (see codes)

33. Location of Event _____

34. Were Other Devices in Use at the Time of the Event (Y or N) ____
If Yes - include list of any relevant devices and their manufacturers in the narrative event description.

EVENT DESCRIPTION

35. In addition to the above event data, provide a narrative description of the event below, including what happened, how the device was involved, and nature of the problem. Attach additional pages if needed.

EVALUATION

36. Was the device Evaluated After the Event (Y or N) ___

37. Method of Evaluation (see codes) ___ ___ ___ ___

38. Results of Evaluation (see codes) ___ ___ ___ ___

39. Conclusion (see codes) ___ ___ ___ ___

40. Certainty of Device as Cause or Contributor to Event (see codes) ___

41. Corrective Actions Taken by Facility (see codes) ___

42. Is the device Available for Further Evaluation (Y or N) ___

43. If Not, Was the Device Destroyed or Disposed Of (Y or N) ___

SOURCE OF REPORT **(IF REPORTED BY A DISTRIBUTOR)**

44. Source Type (see codes) _____

45. Source Name _____

46. Address

47. Phone:_____ 48. City _____

49. State _____ 50. Zip Code _____

USER FACILITY OR DISTRIBUTOR CONTACT IDENTIFICATION

51. Contact Name _____

52. Title_____

53. Address _____

54. Phone _____ 55. City _____

56. State _____ 57. Zip Code _____

58. Date of This Report MM/DD/YY _____

Reporter Signature _____

APPENDIX J

TEST FORM CODES

Item 19 1. CRITICAL 2. FAIR 3. SATISFACTORY 9. UNKNOWN

Item 24 1. Distributor
2. Factory trained, authorized, or owned service organization
3. Independent service organization
4. Independent factory trained or authorized service organization
5. manufacturer
6. User facility Biomedical Department
9. Unknown
0. Other

Item 32

001	Physician
002	Nurse
100	Other healthcare Professional (unspecified)
101	Audiologist
102	Dental Hygienist
103	Dietician
104	Emergency Medical Technician
105	Medical technologist
106	Nuclear Medicine Technologist
107	Occupational Therapist
108	Paramedic
109	Pharmacist
110	Phlebotomist
111	Physical Therapist
112	Physician Assistant
113	Radiologic Technologist
114	Respiratory Therapist
115	Speech Therapist
300	Other Caregivers (Unspecified)
301	Dental Assistant
302	Home Health Aide
303	Medical Assistant
304	Nursing Assistant
305	Patient
306	Patient family member or friend
307	Personal care assistant
400	Service and Testing Personnel
401	Biomedical Engineer

	402	Hospital Service Technician
	403	Medical Equipment Company Technician/Representative
	404	Physicist
	405	Service Personnel
	499	Unattended
Item 33	500	Hospital
	501	Catheterization Suite
	502	Critical Care Unit
	503	Dialysis Unit
	504	Emergency Room
	505	Examination Room
	506	Pathology Department
	507	Maternity Ward - Nursery
	508	Operating Room
	509	Outpatient Clinic
	510	Patients Room or Ward
	511	Radiology Department
	600	Ambulatory Health Care Facility
	601	Ambulatory Surgical Center
	602	Blood Bank
	603	Bloodmobile
	604	Catheterization Lab
	605	Chemotherapy Center
	606	CLINIC
	607	Dialysis Center
	608	Drug Clinic
	609	Imaging Center - Mobile
	610	Imaging Center - Stationary
	611	Laboratory
	612	Mobile Health Unit
	613	MRI Centers
	614	Psychiatric Center
	615	Tuberculosis Clinic
	616	Urgent Care Center
	700	Long-term Care Facility
	701	Hospice
	702	Nursing Home
	703	Psychiatric Facility
	704	Rehabilitation Center
	705	Retirement Home
	810	Patients Home
	820	In Transient to User facility
	830	Public Venue Unspecified
	831	Outdoors

832 Park
833 Playground
834 Public Building
835 School
836 Street
9 Unknown
0 Other

Item 37 Device Evaluated

01 Actual device involved in incident was evaluated
02 A device from the same lot of the actual device involved in the incident was evaluated

Type of Evaluation Performed

11 Computer hardware performance tests conducted
12 Computer software performance tests conducted
20 Electrical tests performed
30 Mechanical tests performed
40 Performance tests performed
50 Visual examination
9 None or unknown
0 Other

Item 38 Category A - Drive

101 Component Failure
102 Computer hardware Problem
103 Computer Software problem
110 Design unspecified
111 Design Inadequate
112 Design Human factors
120 Electrical problem unspecified
121 Short Circuit
122 Open Circuit
131 End of Life
132 End of Life Premature
141 Expected wear and deterioration
142 Failure to cycle
143 Foreign material contamination
144 Inadequate quality assurance
145 Insufficient lubrication
146 Insulation deterioration
150 Labeling Problems
151 Labeling Difficult to read
152 Labeling incomplete
153 Labeling difficult to understand
154 Labeling service manual
155 Labeling user instruction manual
156 Labeling on package
157 Labeling package insert

158 Labeling inadequate instructions for use
159 Labeling incorrect instructions for use
161 Loss of Lubrication
170 Manufacturing
181 Material degradation or deterioration
191 Mechanical Problem,
192 Out of Specification
194 Sterilization
195 Storage or shipment
196 Telemetry failure
9 None or Unknown
100 Other

Category B Use of Device

201 Failure to service
202 Failure to follow instructions
203 Incorrect technique procedures
204 Mated with incompatible equipment
205 Misapplication of device
210 Modification of device unspecified
211 Modification by user
212 Modification by authorized organization
213 Modification by other service organization
215 Modification by distributor
220 Reuse of device unspecified
221 Reused non-reusable device
222 Reused device beyond labeled specifications
230 Used according to labeled indications
9 Unknown
200 Other

Category C Physiological Procedural Factors

310 Anticipated unspecified Physiological procedure
311 Anticipated adverse reaction - long term
312 Anticipated adverse reaction - short term
313 Inherent risk of procedure
314 Known long term complication of procedure
315 Known short term complication of procedure
316 Patient’s condition
321 Caused by another device
322 Related to another device
331 Environmental factors
332 Improper atmosphere
333 Diagnosis contradicted use of device
334 Support System problem
340 Unanticipated unspecified Physiological procedure

341 Unanticipated adverse reaction - long term
342 Unanticipated adverse reaction - short term
343 Unanticipated long term complication
344 Unanticipated short term complication
9 Unknown or none

Category D - Device Component or Subassembly Failures

Device Specific Codes

Anesthesia Machine

401 Absorber
402 Actuator
410 Alarm
411 Alarm - audible
412 Alarm - power
413 Alarm - pressure
420 Bacterial filter
421 Battery
422 Breathing circuit
423 CO2 monitor
424 Cylinder
425 EKG monitor
426 Flowmeter
427 Gas scavenging
428 Humidifier
429 Oximeter
430 Oxygen analyzer
431 Spirometer
440 Valve
441 Valve - control
442 valve - directional
443 Valve - PEEP
444 Valve - relief
445 Valve - selector
450 Vaporizer

Endotracheal and Tracheal Tubes

461 Flange
462 Luer valve
463 Obturator
464 Pilot balloon valve
465 Stylet

Resuscitator

470 Valve
471 Valve - exhalation
472 Valve - inhalation

473 Valve - PEEP
474 Valve - relief
9 None or Unknown

Ventilator

500 Alarm
511 Alarm - assembly
512 Alarm - audible
513 Alarm - high inspiratory pressure
514 Alarm - low inspiratory pressure
515 Alarm - oxygen pressure
516 Alarm - power
517 Alarm - visual
518 Alarm - volume
530 Analog
531 Battery
532 Circuit Board
533 Conversion
534 CPU board
535 Cylinder valve
536 Diode
537 Display board
538 Exhalation filter
539 Heater
540 Humidifier
541 Integrated circuit
542 Light emitting diode
543 Limit switch
544 Logic board
545 Mother board
546 Motor
547 PC board
548 Potentiometer
550 Pressure sensor
551 Pressure tubing
552 PROM
554 Solenoid
555 Sono - alert
556 Stepper motor
557 Transducer
558 Transistor
570 Valve
571 Valve flap
572 Valve flow
573 Valve inlet port

574 Valve inspiratory
575 Valve outlet port
576 Valve PEEP
577 Valve pressure limit
578 Valve relief
579 Valve safety
580 Wiring harness
9 None or unknown
500 Other

Catheter and Transducers

611 Balloon
612 Cap
613 Hub
614 manifold
615 Port
616 Stopcock
617 Y-piece connector

Heart Valve

631 Ball
632 Cage
633 Cusp
634 Disc
635 Leaflet
636 Pivot
637 Prong
638 Stent

Electrical Lead

641 Insulation

Pacemaker

671 Battery failure
672 Adapter failure
673 Early EOL, RRT indicator
674 Electrode failure
675 Hybrid circuit failure
676 IC failure
677 Magnet response failure
678 Programming failure
679 Rate - modulated pacing sensing failure
680 Telemetry failure
9 None or unknown
600 Other

General Codes (all devices)

701 Alarm failure
703 Analog display
704 Battery pack
705 Cable
706 Cassette
707 Charger
709 CO2 monitor subassembly
710 Component failure
711 Connector or adapter
712 Switches
713 CRT/VDT monitor failure
714 Defibrillator paddles
715 Defibrillator subassembly
716 Diaphragm
717 Digital display
718 Discrete component
719 EKG/ECG subassembly
720 Electrode
721 Fail-safe systems
723 Foot switch
724 Gauges/meters
725 Guidewire
726 Hollow fiber
727 Integrated circuit board
728 Integrated chip
729 Keyboard
730 Membrane
733 Motor
734 02 monitor
735 Oximeter
736 Potentiometer
737 Power cord
738 Power supply
740 RAM and ROM memory
741 Recorder
742 Relay
743 Telemetry equipment
744 Transducer
745 Transformer
746 Tubing
747 Valve
9 None or unknown
700 Other